

CHILD ASSENT SAMPLE (Drug Study)

USE AN ABBREVIATED STUDY TITLE TO IDENTIFY

Dr. _____ is doing a research study to find out if a new medicine works in making kids better when they have (*name of condition in common term*). You are being asked if you want to be in this research study because you have (*name of condition*).

If you decide that you want to be in this research study, this is what will happen to you:

1. Dr. _____ will give you some medicine to take for the next 5 days. It might be the new medicine or it might be the medicine that you would get if you weren't in this research study. You won't know which one you get and Dr. _____ won't know what you get either.
2. You will have to have a needle stick today (like a shot) to take some blood out of your arm. Dr. _____ has to take some more blood out of your arm in 5 days to find out if the medicine you are taking is making you better. And even if you don't want to do the research study, you are still going to get a needle stick today because you're sick.
3. If you still aren't getting better after 5 days, Dr. _____ will (*tell them what to expect such as being another medicine or other treatment*).

Sometimes kids don't feel good after they take the medicine. They might feel these things:

- ♦ An upset stomach a headache
- ♦ Very sleepy get a rash on their skin

If you feel any of these things, be sure to tell your mom or dad.

You don't have to be in this research study if you don't want to. Nobody will be mad at you if you say no. Even if you say yes now and change your mind after you start doing this study, you can stop and no one will be mad.

Be sure to ask Dr. _____ to tell you more about anything that you don't understand.

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☐

Yes, I will be in this research study.

☐

No, I don't want to do this.

Write your name on this line _____

Date

CHILD ASSENT SAMPLE (NON-MEDICAL RESEARCH)

USE AN ABBREVIATED STUDY TITLE TO IDENTIFY

Dr. _____ is doing a research study to find out if a new way of treating you is better than the kind of treatment kids normally have for (*name of condition in common term*). You are being asked if you want to be in this research study because you have (*name of condition*).

If you decide that you want to be in this research study, this is what will happen to you:

1. Dr. _____ will ask you some questions today and he will also ask your mom or dad some questions. Then he will play a game with you. You will be here for about one hour today.
2. You will come back to see Dr. _____ in 2 weeks and he will ask you and your parents some more questions. This visit will only be about 1/2 an hour long.

You don't have to be in this research study if you don't want to. Nobody will be mad at you if you say no. Even if you say yes now and change your mind after you start doing this study, you can stop and no one will be mad.

Be sure to ask Dr. _____ to tell you more about anything that you don't understand.



☐ Yes, I will be in this research study.

☐ No, I don't want to do this.

Write your name on this line

Date

NOTE TO INVESTIGATOR: *Keep it very simple. Tell what the word means, don't use the bigger word. Use short sentences in the common vernacular of kids. Grammar isn't as important as their understanding what you mean. If you know a 7 year old, write the assent as if you were telling it to that child. Include only what will happen with the research, not with their normal therapy. But don't overwhelm them with details. Keep it short and to the point. And ALWAYS tell them that no one will be mad at them if they decide to say no.*